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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,182	11/26/2001	Jan Matthijs Jetten	BO 42503	9536
466	7590 06/11/2003			
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR			EXAMINER	
ARLINGTON, VA 22202		JR	MCINTOSH III, TRAVISS C	
			ART UNIT	PAPER NUMBER
			1623	1
			DATE MAILED: 06/11/2003	14

Please find below and/or attached an Office communication concerning this application or proceeding.

	Annligati	n N	File Capy
	Applicati		Applicant(s)
Offic Action Summary	09/914,1		JETTEN ET AL.
, and a summary	Examin		Art Unit
The MAILING DATE of this communic	Traviss C	McIntosh	1623
Peri df r Reply	auon appears on me	e c versneet with the d	corresp ndenc address
A SHORTENED STATUTORY PERIOD FOR THE MAILING DATE OF THIS COMMUNICATE OF THIS COMMUNIC	A HON. 37 CFR 1.136(a). In no evication. days, a reply within the state tory period will apply and will apply apply and will apply apply apply and will apply apply apply apply and will apply apply apply and will apply app	ent, however, may a reply be tin utory minimum of thirty (30) day ill expire SIX (6) MONTHS from	nely filed s will be considered timely. the mailing date of this communication
1) Responsive to communication(s) filed	l on 13 May 2003		
0-157	This action is	non-final	
Since this application is in condition for closed in accordance with the practice Disposition of Claims	or allowance excent	for formal matters an	osecution as to the merits is 53 O.G. 213.
4)⊠ Claim(s) <u>19-39</u> is/are pending in the ap	pplication.		
4a) Of the above claim(s) is/are		sideration	
5) Claim(s) is/are allowed.	The second secon	ioloci allori.	
6)⊠ Claim(s) <u>19-39</u> is/are rejected.			
7)⊠ Claim(s) <u>27</u> is/are objected to.			
8) Claim(s) are subject to restriction	n and/or election re	quirement	
Application Papers		qui ement.	
9)☐ The specification is objected to by the Ex	xaminer.		•
10)☐ The drawing(s) filed on is/are: a)[accepted or b)	bjected to by the Exam	iner
Applicant may not request that any objection	on to the drawing(s) t	e held in abevance. See	37 CER 1 85(a)
11) Ine proposed drawing correction filed on	າ is: a)∐ ap _l	proved b)⊡ disapprov	ed by the Examiner.
If approved, corrected drawings are require	ed in reply to this Offic	ce action.	•
12)☐ The oath or declaration is objected to by	the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120			
13) Acknowledgment is made of a claim for	foreign priority und	er 35 U.S.C. § 119(a)-	(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:		,	
 Certified copies of the priority doc 	uments have been	received.	
2. Certified copies of the priority doci			ı No.
Copies of the certified copies of the application from the Internation See the attached detailed Office action for	ne priority documen	ts have been received	in this National Stage
14) Acknowledgment is made of a claim for do	omestic priority und	er 35 U.S.C. § 119(e)	(to a provisional application)
a) ☐ The translation of the foreign langua 15)☐ Acknowledgment is made of a claim for do Attachment(s)	ge provisional appli	ication has been receive	rod
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-94) Information Disclosure Statement(s) (PTO-1449) Paper Note: Patent and Trademark Office	48) si	Interview Summary (P Notice of Informal Pate Other:	TO-413) Paper No(s) ent Application (PTO-152)
TO 200 (Dec. 04.04)	fice Action Summary	r	Part of Paper No. 14

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DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

The Amendment filed May 13, 2003 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claim 39 has been amended.

Remarks drawn to rejections of Office Action mailed January 13, 2003 include:

Double Patenting rejections: rendered moot by applicants' amendments and have been withdrawn.

112 2nd paragraph rejections: rendered moot by applicants' amendments and have been withdrawn.

103(a) rejections: rendered moot as the date of the priority document does not allow it to be used as prior art against the instant application, and has been withdrawn.

An action on the merits of claims 19-39 is contained herein below.

The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

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Double Patenting

Claims 31, 32, and 34-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-15 of copending Application No. 09/913,603 ('603). Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to oxidized carbohydrates which are not patentably distinct.

Independent claim 31 of the instant application is drawn to an oxidized carbohydrate being selected from disaccharides, oligosaccharides and polysaccharides of the glucan, mannan, galactan, fructan, and chitin types and carbohydrate glycosides, containing at least 1 cyclic monosaccharide chain group carrying a carbaldehyde group per 25 monosaccharide units and per average molecule and optionally being a carboxyalkyl derivative obtained by further oxidation or carboxylation, thus having carboxy and/or carboxymethyl groups. Independent claim 10 of '603 is drawn to an oxidized carbohydrate being selected from disaccharides, oligosaccharides and polysaccharides of the alpha-glucan, mannan, galactan, fructan, and chitin types and carbohydrate glycosides, containing at least 1 cyclic monosaccharide chain group carrying a carbaldehyde group per 25 monosaccharide units and per average molecule and further containing carboxyl and/or carboxymethyl groups. Dependent claim 36 the instant application adds the limitation of the oxidized carbohydrate further containing carboxyl and/or carboxymethyl groups. It would have been obvious to one of ordinary skill in the art that these oxidized carbohydrates are substantially overlapping, and identical in parts, wherein the claims of '182 and the claims of the instant encompass a broad class of compounds, wherein the only species not encompassed by both is that of the beta-glucan type.

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Claim 32 of the instant application and dependent claim 11 of copending '603 both provide the limitation wherein the carbohydrate contains at least 5 monosaccharide units per average molecule.

Dependent claim 34 of the instant application and dependent claim 12 of copending '603 both limit the oxidized carbohydrate wherein at least part of the carbaldehyde groups has been converted to a group with the formula –CH=N-R or CH₂-NHR, wherein R is hydrogen, hydroxyl, amino, or a group R¹, OR¹, or NHR¹, in which R¹ is C₁-C₂₀ alkyl, C₁-C₂₀ acyl, a carbohydrate residue, or a group coupled with or capable of coupling with a carbohydrate residue.

Dependent claim 35 of the instant application and dependent claim 13 of copending '603 both limit the oxidized carbohydrate wherein at least a part of the carbaldehyde groups has been converted to a group with the formula –CH(OR³)-O-CH₂-COOR² or –CH(-O-CH₂-COOR²)₂, in which R² is hydrogen, a metal cation or an optionally substituted ammonium group, and R³ is hydrogen or a direct bond to the oxygen atom of dehydrogenated hydroxyl group of the carbohydrate.

The compounds of the instant application must contain new and non-obvious variations over the copending applications to be patentably distinct.

This is a <u>provisional</u> obviousness-type double patenting rejection.

Claim Objections

Claim 27 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, the recitation of what is produced is of no patentable import to the methodological steps of the process as claimed.

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Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 19 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

Claims 19-30 and 37-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A written description analysis involves three principle factors:

- 1) Field of the invention and predictability of the art,
- 2) Breadth of the claims, and

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3) For each claimed species/genus, possession of the claimed invention at the time of the filing.

The breadth of the claims is such that the support in the specification is not adequate for the claims. To provide adequate support for the breadth of the claims, applicant would have to provide sufficient evidence. An adequate representation of species requires that the species which are expressly described are indeed recognized in the art as representative of the entire genus. What constitutes "adequate representation" is an inverse function of the predictability in the art in question (should be supported by the state of the art). The written description requirement for a claimed genus, which in the instant application is "a process for oxidizing a non-cellulose primary alcohol" which comprises any and every compound containing a primary alcohol function except for cellulose, may be satisfied through sufficient description of an adequate representation of species by functional characteristics sufficient to show applicant was in possession of the claimed genus.

As established by applicant's response filed May 13, 2003, page 2, when discussing obviousness of the method claimed in the instant application in comparison to an identical method on cellulose, applicant's state that "the claimed invention relates to oxidizing a non-cellulose primary alcohol... as the claims of the '596 application are all directed to cellulose, applicants believe the claimed invention cannot be obvious in view of the cited claims".

Applicants do not argue the methodological process steps, or reagents used are different, only the starting material is different. In view of these statements and upon further review of the instant application, applicants have not described the claimed genus in such a way as to show they had possession of the claimed invention at the time of filing. Currently, the examiner believes

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applicants have acceptably shown a method of oxidizing starch and/or pullulan, which is not representative of the entire genus of "non-cellulose primary alcohols".

As such, a skilled artisan would not recognize the current evidence of record as sufficient evidence. As such, there is not seen any data or correlative prior art evidence which supports applicant's claim that at the time of record they were in possession of the invention as asserted in the claims. Applicant's clearly articulating how a method which was shown to be effective only on pullulan and starch would be effective and obvious on all other compounds containing a primary alcohol and would not be effective and obvious on cellulose would obviate the rejection instantly at hand.

Claims 31-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are rejected for the same reasons as set forth supra, wherein applicant claim the broad genus of oxidized carbohydrate selected from the group consisting of disaccharides, oligosaccharides, or polysaccharides of the alpha-glucan, mannan, galactan, fructan, chitin types, and carbohydrate glycosides. It is believed applicants only had possession of an oxidized starch and an oxidized pullulan at the time the invention was filed.

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Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 39 is directed to an oxidized carbohydrate of the beta-glucan type. Cellulose is a beta-glucan carbohydrate. Applicant's claims and arguments clearly articulate that this invention is drawn to a process for oxidizing **non-cellulose** primary alcohols, therefor applicant could not have had possession of this broad genus of "saccharides of the beta-glucan type".

Claims 19-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 provides for the use of a nitroxyl compound, but, since the claim does not set forth any steps involved in the method/process as claimed, which is "a process for oxidizing a non-cellulose primary alcohol", it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 25, 26 and 28-30 are indefinite wherein the recitation in a dependent claim of the source of an active agent to be used in a method from which said claim depends, wherein the "source of the active agent" does not result in a patentably distinguishable methodological and manipulative difference in how said active agent's source impacts the method from which it

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depends, renders the claim(s) in which it occurs and which depend therefrom indefinite for failing to distinctly articulate how such a recitation further limits the method from which said dependent claim(s) applicant regards as the invention. Clearly articulating how this recitation of "the primary alcohol is in a steroid", or "in textile fibers", for example, would methodologically impact the process from which it depends would obviate the instant rejection.

Claims 31-33 and 39 are indefinite wherein the claims recite "per average molecule". It is unclear as to what meant by "per average molecule". There are no groups defined wherein an average could be obtained, and averages can be determined by various forms, i.e. mean, median, mode. Clarity is required.

All instances wherein "cyclic monosaccharide chain group" occur, i.e. claim 31, are indefinite. It is unclear what is meant by "cyclic monosaccharide chain group". It is unclear how a cyclic monosaccharide can be a chain group. Clarity is required.

Claim 34 is indefinite wherein the claim reads "at least a part of the carbaldehyde groups has been converted...". Is part of the carbaldehyde group converted, i.e. R-COH $\rightarrow R$ -COOH, or are only a portion of the carbaldehyde groups on the saccharide converted? Clarity is respectfully requested. Additionally, if the claim reads as a portion of the carbaldehyde groups on the saccharide being converted, the claim does not properly depend from claim 10, as at least part of includes converting all of the carbaldehyde groups, therein leaving none left and being in improper dependency.

All claims which depend from an indefinite claim are also indefinite. Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by BeMiller et al. (US Patent 3,632,802).

The claims of the instant application are drawn to an oxidized carbohydrate containing at least 1 cyclic monosaccharide chain group carrying a carbaldehyde group per 25 monosaccharide units and further comprising carboxyl and/or carboxymethyl groups. Further, the oxidized carbohydrate contains at least 5 monosaccharide molecules.

BeMiller et al. teach to oxidize starch (which contains thousands of monosaccharide units) with chromic anhydride or with sulfuric acid thereby introducing aldehyde, ketone, and carboxyl groups (column 2, lines 3-7). The recitation of an oxidized starch with aldehyde, ketone, and carboxyl groups reasonably describes the compound claimed as this indicates that the aldehyde groups are obtained by oxidizing a primary alcohol function on the anomeric carbon, and additionally, some are further oxidized to carboxyl groups. The ketone groups are the result of the C2 and C3 alcohol groups (2,3-glycol group) being oxidized.

Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re*

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Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Traviss C. McIntosh June 5, 2003 James O. Wilson

Supervisory Patent Examiner

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